REMARKS

The Applicants would respectfully like to bring to the attention of the Examiner that claims 1- 11, 15 and 16 are currently pending in the application. The Examiner identifies in the present Office Action that claims 1- 6, 15 and 16 are currently pending in the Application. However, claims 1-11 had been elected for prosecution on July 25, 2003 by the Applicants which group was identified as an invention that could be elected in total, in the Office Action requiring restriction, that was mailed to the Applicants by the Examiner on June 26, 2003. Claims 12-14 have thus previously been withdrawn.

Claim 16 is amended to omit the term"comprising" to describe the ranges of the salmon calcitonin and crospovidone components in the formulation claimed therein and replace them with the words "is present in an amount of from". Claim 16 is also amended to correct the range of crospovidone. Support for these changes may be found in the Specification on page 4 in lines 15 – 17 and lines 29-32.

Claims 17, 18 and 19 are newly added in order to better define the particular aspects of the compositions of the invention. Support for the newly added claims may be found in the Specification on page 4 in lines 15 – 17 and lines 29-32.

The Examiner has rejected claims 1- 6 and 15 -16 under 35 U.S.C. § 103(a) over Bay et al., WO 0059863, Leone-Bay et al. '536 or Leone-Bat et al. '647 taken with GB 2295966 or WO 0057857, and Purkayastha et al, or EP 438147. The Applicants respectfully disagree with the rejection and request that the Examiner withdraw the rejection of claims 1-6 (11), 15 and 16 based thereon for the following reasons.

The Applicants' invention is exemplified by the finding that a composition which contains crospovidone or povidone, in addition to a pharmacologically active agent, for example, a peptide such as salmon calcitonin, in combination with the delivery agent 5-CNAC will be more bioavailable than a similar composition which does not include crospovidone or povidone. In fact, crospovidone or povidone may improve bioavailability by more than four–fold over a similar composition that does not contain crospovidone or povidone. The results of administration of several comparative compositions of salmon calcitonin plus 5-CNAC compositions to primates, are shown in Example 2 in Table 2 on page 10 of the Specification. In Example 2, Comparative Composition A, which is the only composition employed which contains crospovidone, shows a an enhancement of Cmax and AUC values by more than four-fold over the non-crospovidone

containing comparative compositions. The increased biovailability can not be attributed to increased amounts of the delivery agent, 5-CNAC in Comparative Composition A (82.23% of Comparative Composition A is 5-CNAC) versus the remaining Comparative Compositions. Comparative Composition C contains about 61% 5-CNAC and Comparative Composition B contains about 50% 5-CNAC but Comparative Composition B has a 40% increase in Cmax values and a 25% increase in AUC values over Comparative Composition C. This aspect of the present invention could not have been foreseen by the references cited by the Examiner.

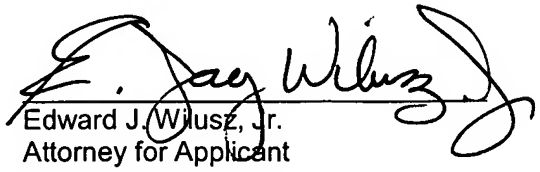
Based on the foregoing Applicants therefore respectfully request that the Examiner withdraw the rejection of claims 1-6 (11), 15 and 16.

The Applicants believe that the application is in condition for allowance and respectfully request early notice to that effect.

It is believed that no additional fees are due in the case however the Examiner is authorized to charge or credit overpayments to Deposit Account No. 19-0134, for fees which are properly assessable in the case, in the name of Novartis Corporation.

If it will advance prosecution of the case the Examiner is urged to telephone the Applicants' undersigned counsel at the number listed below.

Respectfully submitted,



Edward J. Wilusz, Jr.
Attorney for Applicant
Reg. No. 52,370

Novartis
Corporate Intellectual Property
One Health Plaza, Building 104
East Hanover, NJ 07936-1080
(862) 778-7960

Date: December 1, 2004